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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,928	02/20/2002	Howard Murad	2267-024	7746

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EXAMINER

KIM, VICKIE Y

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 01/14/2004

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/077,928

Applicant(s)

MURAD, HOWARD

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☒ Claim(s) 23-34 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment filed 10/16/03. Upon entering the amendment, the claims 23-31 are amended and the claims 1-22 are canceled.

New claims 32-34 are added.

2. The claims 23-34 are pending and presented for the examination.

Response to Arguments

3. Applicant's arguments with respect to claims 23-31 have been considered but they are not persuasive and the moot in view of new ground of rejection due to the scope changes made in amended claims. The detailed response will be following after art rejection.

Claim Rejections - 35 USC § 102/103

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 23-34 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rothman et al(WO 91/02538).

The claims are drawn to a method of treating, preventing, or managing a dermatological conditions(e.g. psoriasis, folliculitis, rosacea, seborrheic dermatitis, dandruff, nail fungus, etc) using a therapeutically effective amount(i.e. 1-20,000mg) of composition comprising hydrogen peroxide, a hydrophilic moisturizing agent, a

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hydrophobic moisturizing agent, an exfoliant, and one or more dermatological agents selected from an antimicrobial agent(e.g. antibacterial, antifungal antiviral, anthelmintic or combinations thereof), or an anti-inflammatory agent .

Claims 25-26 further require topical administration (e.g. gel, paste, cream, shampoo, etc).

Claim 29 further requires a beneficial additive such as an antioxidant.

Rothman et al(WO'538, hereafter) teaches a therapeutic composition used effectively in hair, skin or nails, and a method of the patented invention for treating skin conditions such as seborrhea, psoriasis, hang nails, decubitus ulcers wherein said composition comprising hydrogen peroxide, moisturizers(e.g. Kerasol®, glycerine), citric acid and antimicrobial agent(e.g. germaben II®), see abstract, examples and claims, especially claim 43 and example 1.

WO'538 also teaches additional antimicrobial agent such as neomycin or bacitracin as a beneficial active agent to enhance the therapeutic effectiveness, see pages 25-26. WO'538 also teaches an antioxidant such as tocopherol, rosemary extract, see page 21. WO'538 further teaches various topical formulations such as gel, cream, lotion, etc, see page 26, 3rd paragraph.

Although the terms used in the cited patent are not exactly same as the terms called by applicants, specifically exemplified compositions(examples 1-8) contain all the critical elements. All the claimed elements and their roles are well taught by the cited patent as mentioned above. For instance, example 1 composition comprises 1.61%

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hydrogen peroxide(as an oxidizing agent, also clean the keratinous tissue and enhance the healing, see page 20); 8.82% Kerasol® (as film-forming protein, also known as a hydrophilic moisturizer, hydrated and cysteine rich keratin that provides additional moisture to the skin and hair, see page 6 and page 15), 0.5%glycerin(known as a hydrophobic moisturizer), citric acid(known as an exfoliant), 2.93% Germaben II ® (known as an antimicrobial agent, see page 25). It is noted that these said components are all mixed and formulated together in a composition, their concurrent administration is inherent. Even if there are some differences in names(different terms) and dosage regimen(i.e. 1-20,000mg), the differences are considered to be minor and the modifications are well within the levels of skilled artisan, wherein they do not influencing the patentability and thus, obvious and well encompassed by the scope of the patented invention.

Thus, all the critical elements required by the instant claims are met by the cited reference and the claimed subject matter is not patentably distinct over the prior art of the record.

.....

In the response, applicants argue that every elements are not taught by the cited reference. However, applicant's argument is not persuasive because the cited reference , in fact, teaches all the elements required by the instant claims(including now amended claims).

In light of specification, the claimed elements of the instant claims are hydrogen peroxide(0.01-6%) in a therapeutically effective amount to cleanse the surface of

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affected area(at page 10); a hydrophobic moisturizer such as glycerine in an amount from about 0.1 to 5%(at page 10); a hydrophilic moisturizer such as hydrolyzed protein, hair keratin amino acids in an amount of 0.01-20% to moisturize the skin by absorbing the moisture to hydrate or facilitate the hydration(at page 11); an exfoliant such as citric acid in an effective amount of 0.1-12%(at page 13-14); and an antimicrobial agent in an amount of 0.01-1.5%(page 16). The critical element of claim 29 is an antioxidant or rosemary extract as an optional additive(s). As mentioned 102/103 rejection, all the critical elements(the compounds and their functional roles) are well taught and thus, the claimed subject matter is anticipated by the cited reference. Because their multi-functional role, a compound is often called in different name but they are considered to be inherently same.

Conclusion

6. No claim is allowed.

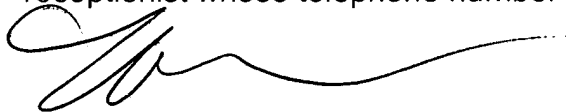
7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,
Primary Patent Examiner
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